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Provider Alert

# Potential for Falsely Low Blood Lead Test Results from Venous Samples Analyzed with LeadCare® Devices

*This safety communication was issued by the U.S. Food and Drug Administration (FDA) on May 17, 2017. Visit* www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm *for additional information.*

The U.S. Food and Drug Administration (FDA) has issued a safety communication warning about the use of Magellan Diagnostics' LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) with venous blood samples because they might result in falsely low test results. FDA is now advising that Magellan Diagnostics' LeadCare® analyzers should no longer be used with venous blood samples. The safety alert does not apply to capillary blood lead test results collected by fingerstick or heelstick.

The Centers for Disease Control and Prevention (CDC) and FDA are assessing the potential public health risk of a negative bias associated with Magellan's lead testing systems. FDA is now warning that Magellan Diagnostics' LeadCare® analyzers should no longer be used with venous blood samples due to the potential for falsely low test results. Not all blood lead tests are affected. Laboratory tests analyzed by inductively coupled plasma-mass spectrometry (ICP-MS) or graphite furnace atomic spectrometry (GFAAS) (also known as electrothermal atomic absorption spectrometry [ETAAS]) are not expected to have resulted in falsely low results. This alert applies to venous blood lead tests conducted using Magellan Diagnostics' LeadCare® analyzers whether the patient is a child or an adult. At this time, the alert does not apply to capillary blood lead test results collected by fingerstick or heelstick using Magellan Diagnostics' LeadCare® analyzers. Children are particularly vulnerable to lead exposure due to the effect on their developing brains and organ systems. CDC is working with public health officials throughout the United States to determine where the analyzers were used and which blood lead test results might be affected.

## Recommendations

CDC recommends that healthcare providers re-test patients who:

- are younger than 6 years (72 months) of age at the time of the alert (May 17, 2017) and
- had a venous blood lead test result of less than 10 micrograms per deciliter (µg/dL) analyzed using a Magellan Diagnostics' LeadCare® analyzer at an onsite (e.g., healthcare facility) or at an offsite laboratory.
- are currently pregnant or lactating women who had a venous blood lead test performed using a Magellan Diagnostics' LeadCare® analyzer.

Re-tests are not recommended if the provider is certain that analyzers other than those described by this Health Advisory were used to analyze the venous blood samples.

## For future blood lead testing, healthcare providers should:

- Send venous samples to Clinical Laboratory Improvement Amendments (CLIA)-compliant laboratories using inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectrometry (GFAAS) (also known as electrothermal atomic absorption spectrometry [ETAAS]) instruments. To identify laboratories approved by NYSDOH Wadsworth Center's to perform Toxicology - Blood Lead Comprehensive testing, see www.wadsworth.org/regulatory/clep/approved-labs.

- Send capillary samples to CLIA-compliant laboratories using any CLIA-compliant analyzer including ICP-MS, GFAAS, or LeadCare® analyzers.

## Additional resources

- CDC Health Alert
  https://emergency.cdc.gov/han/han00403.asp

- CDC Clinician Outreach and Communication Activity (COCA) conference call regarding the Health Alert
  https://emergency.cdc.gov/coca/calls/2017/callinfo_052417.asp

- CDC Flow Diagram for Determining Potentially Affected Lead Tests and the Need for Retesting
  www.cdc.gov/nceh/lead/docs/Blood_Lead_Tests_Flowchart.pdf

- CDC Lead Poisoning Prevention Program
  www.cdc.gov/nceh/lead/

- CDC Lead and Multi-element Proficiency Program
  www.cdc.gov/labstandards/lamp.html

- NYSDOH Lead Poisoning Prevention Program
  www.health.ny.gov/environmental/lead/